Special 510(k) Summary

Name of Submitter: OsteoMed

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Contact Person: Blesson Abraham

DEC 0 2 2013

Date Prepared: November 5, 2013

Device Proprietary Name: 1st MTP Plate

Device Common Name: Foot Plate

Classification Name: 21 CFR 888.3030: Single/multiple component metallic bone fixation appliances and accessories

Product Code: HRS

Predicate Devices:

OsteoMed ExtremiLOCK Foot Plating System, K131445
Classification Name: Single/multiple component metallic bone fixation appliances and accessories (**21CFR 888.3030, Product Code HRS**)
Device Class: **II**

Summary:

Device Description:
The 1st MTP Primary and Transfix plates are designed as part of the OsteoMed ExtremiLOCK Foot Plating System. The system consists of plates of various shapes and sizes featuring compression, locking, elongated or compression elongated holes, angulated locking, non-locking and cannulated screws, implantable K-Wires, washers, and appropriate instrumentation. Modifications to plates of the subject system include increasing/decreasing the thickness of the plates, material changes, and addition of features.

The implants of the OsteoMed ExtremiLOCK Foot Plating System are made from Titanium (ASTM F-67) or Titanium alloy (ASTM F-136). Surgical instrumentation is provided to facilitate modification, insertion, and removal of implants. The instrumentation is made from various grades of stainless steel, anodized aluminum, and/medical grade polymer.

Intended Use:
The OsteoMed ExtremiLOCK Foot Plating System is indicated for use in trauma, general surgery, and reconstructive procedures of the foot, ankle or other bones appropriate for the size of the device.

The OsteoMed ExtremiLOCK Foot Plating System implants are intended for single use only.

Technological Characteristics:
The OsteoMed ExtremiLOCK Foot Plating System is recommended for fixation/reconstruction of small fragment bones, forefoot, mid-foot, rear-foot, ankle or other bones appropriate for the size of the device.

ExtremiLOCK implants are manufactured from Titanium (ASTM F-67) or Titanium alloy (ASTM F-136), the same materials used in the manufacture of the predicate devices. These materials are biocompatible.

Performance/Clinical Data:
The 1st MTP Primary and Transfix plates were compared to the OsteoMed ExtremiLOCK Foot Plating System, K131445, plates. The implants underwent verification evaluation to ensure that the design features met the required mechanical strength criteria for their intended use. The intended use of the OsteoMed ExtremiLOCK implants remains the same with the addition of the 1st MTP Primary and Transfix plates.

Performance equivalence was shown through the verification comparison to the predicate devices.

Clinical Testing is not required to support substantial equivalence.

Substantial Equivalence:

A design, dimensional, and performance comparison was performed to establish substantial equivalence to the legally marketed predicate devices listed in this summary. The basis of substantial equivalence for this device is based on similarities in intended use, material, function, performance, design, technology and operational principles to the OsteoMed ExtremiLOCK Foot Plating System (K131445).

The basis of substantial equivalence of the 1st MTP Primary and Transfix plates to the OsteoMed ExtremiLOCK Foot Plating System, K131445, is based on the similarities in design, technology, material, function, sterilization, and intended use. OsteoMed believes that the non-clinical evaluation demonstrate that the device is as safe, and effective as the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

December 2, 2013

OsteoMed
Ms. Blesson Abraham
Regulatory Affairs Specialist
3885 Arapaho Road
Addison, Texas 75001

Re: K133437
Trade/Device Name: OsteoMed ExtremiLOCK Foot Plating System
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/multiple component metallic bone fixation appliances and accessories
Regulatory Class: Class II
Product Code: HRS
Dated: November 5, 2013
Received: November 7, 2013

Dear Ms. Abraham

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Lori A. Wiggins

for
Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K133437

Device Name: OsteoMed ExtremiLOCK Foot Plating System

Indications for Use:

The OsteoMed ExtremiLOCK Foot Plating System is indicated for use in trauma, general surgery, and reconstructive procedures of the foot, ankle or other bones appropriate for the size of the device.

The OsteoMed ExtremiLOCK Foot Plating System implants are intended for single use only.

Prescription Use ___X____ (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Elizabeth L. Frank -S

Division of Orthopedic Devices